



Long-Acting Options: Lessons Learned from Prevention to Inform Treatment

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Agenda

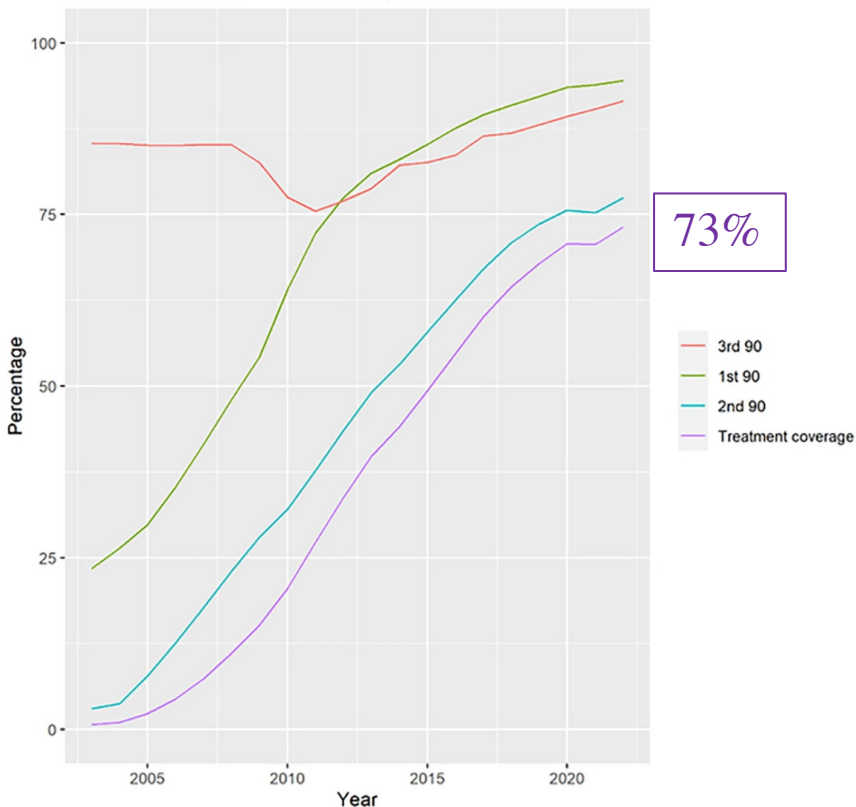
- 1. HIV update and current LA-biomedical strategies**
- 2. User-Journey and “bumps” on the adherence road**
- 3. Access**
- 4. Choice- providing options without coercion**
- 5. Tools to support adherence**

1. HIV update: South Africa 2022

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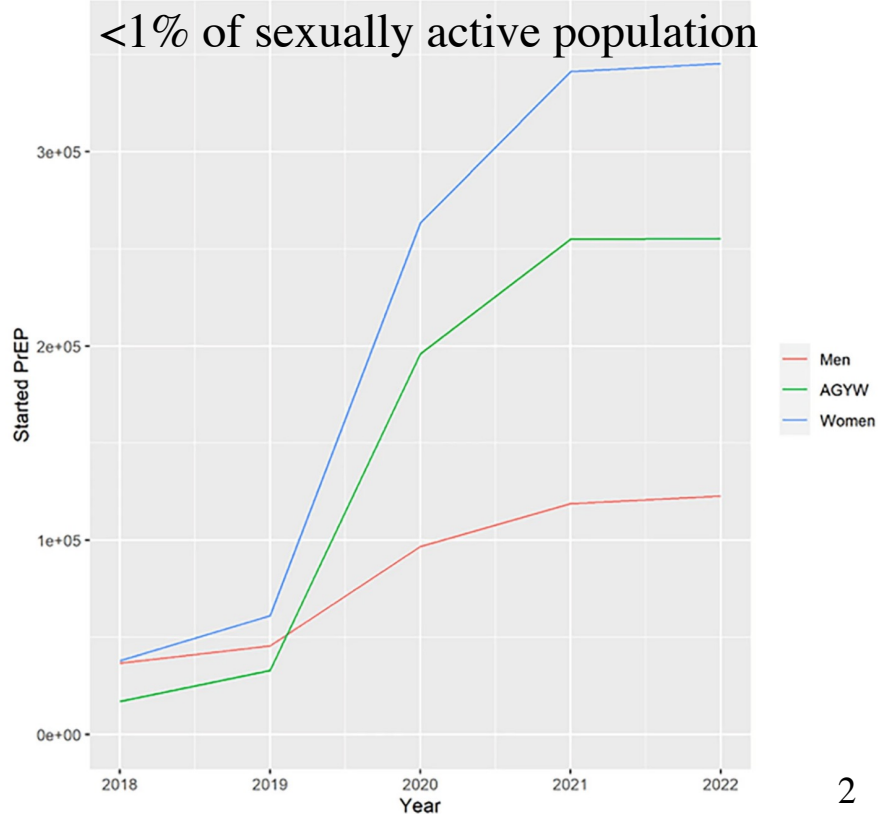


90-90-90 and treatment coverage



Data sourced from Themisa 4.6. Graph by Spotlight.

People starting PrEP over time



Data sourced from Themisa 4.6. Graph by Spotlight.



LA-biomedical interventions for PrEP & Rx



**2-month IM
injection**



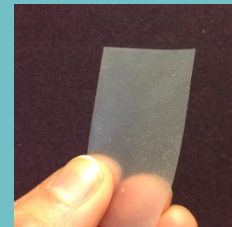
**1 month ring
injection**

✓ **Approved**

○ In development



**1-year
Implant**



**1-month
film**



**Weekly-monthly
Pill**



**6-month SC
injection**



**3-month ring
injection**

Pros and Cons of LA-Injectables

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Purpose	Pros	Cons
PrEP	Longer dosing intervals Invisibility/discretion/privacy DOT for injection compliance Modality preferred by users Low user burden (set it and forget it)	PK tail requires alternate coverage ISR/painful to inject- Persistent mark? HCP time burden/skills required Highly medicalized option/clinic attendance Non-reversible
Rx	<i>Same as above</i>	Risk of virologic failure ISR/painful to inject Burden on HCP and users Requires skilled staff /high level of monitoring needed (baseline resistance, HBV, TB, DDI, etc)



Cab-LA: adherence & preference in PrEP trials

Pivotal trials	HPTN-083 (MSM+TGW)	HPTN-084 (CGW)
Injection phase (p-y covered by injections)	91.5%	93%
Truvada arm: TFV concentration >40ng/ml (daily dosing)	74.2%	46%
Preference Cab-LA vs. Truvada (preliminary data)	96% (in US)	~88%



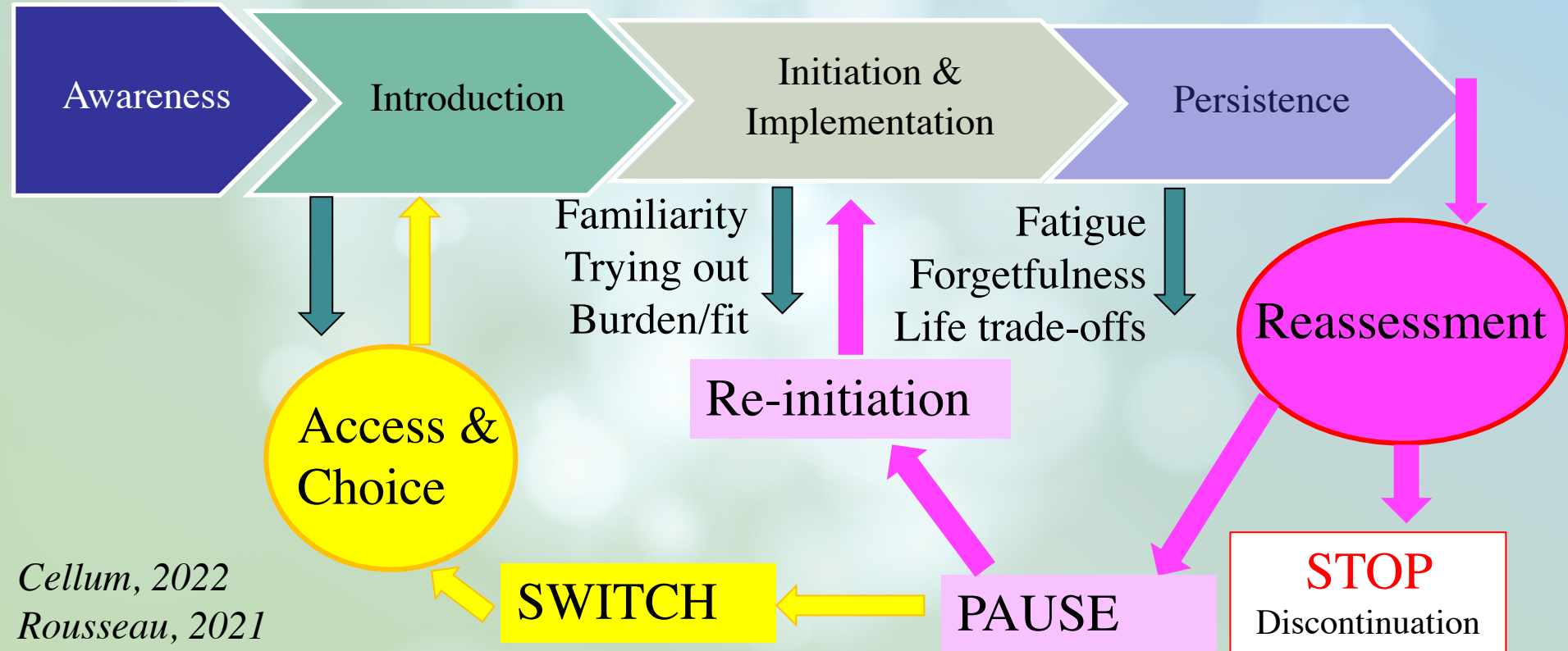
HPTN-083:

OLE decreased adherence in both Cab-LA & Truvada groups:

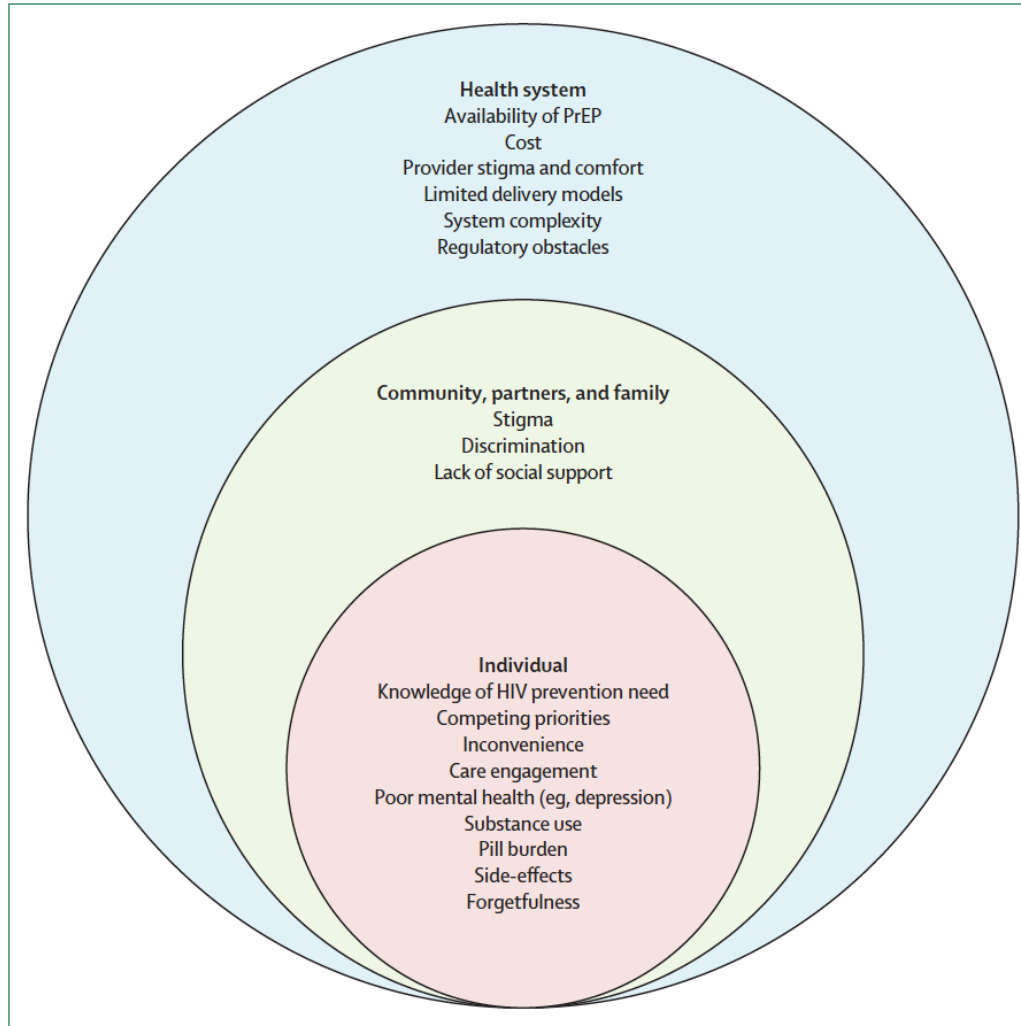
Inadequate protection	Blinded phase	OLE
<4 doses/wk of Truvada	27%	61%
Missed injection	9%	19%



2. User Journey(s) with PrEP Adherence



Cellum, 2022
Rousseau, 2021
O'Rourke, 2021



*Haberer, Lancet
HIV, 5/2023*

Figure 1: A socioecological model of barriers to PrEP adherence

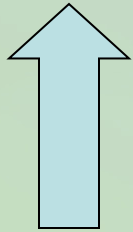


3. Access

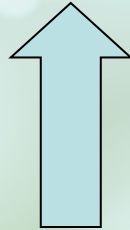
- Adherence to a medication is impossible without access.
- Moreover, we need to go beyond providing current users with more options:
 - > Increased equity means reaching those unable to use current options so as to expand coverage
 - > Need for delivery systems innovations
 - Community delivery (of PrEP or Rx) brings PrEP to the user, meeting them where they are physically and mentally.



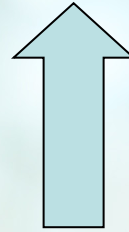
Barriers to access for LA-injection



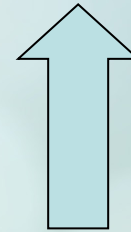
Affordability



Time & cost
of travel to clinic
Wait time
Time away from job



Forgetting
to Schedule or
go to the clinic
appointment



HCP friendliness,
skills, cultural
competence

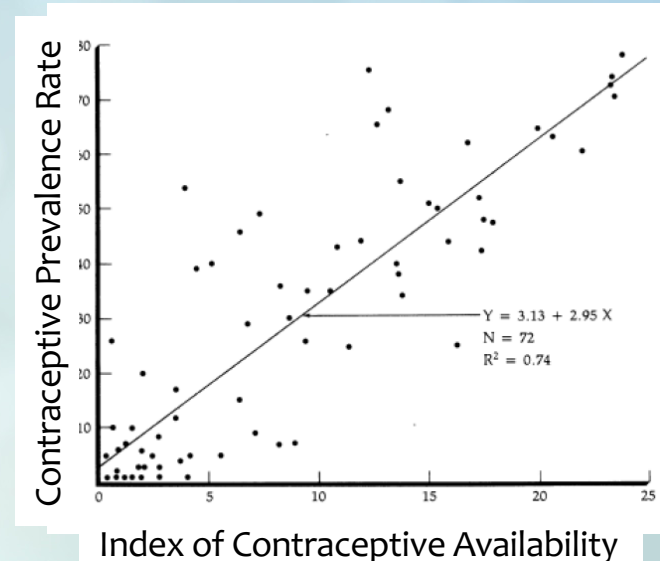


4. Choice

Options → Choices → Coverage → Impact

Benefits of Product Choice for Contraception

- WHO Systematic Review
- 231 articles, limited high quality evidence
- **Increased choice** associated with:
 - Increased contraception uptake
 - Better health outcomes (fewer pregnancy, STIs)
- Those given contraceptive choice continue their chosen method to a greater degree than those denied choices
- Contraceptive needs and choices vary over a person's reproductive life



12% increase contraceptive prevalence for EACH additional method

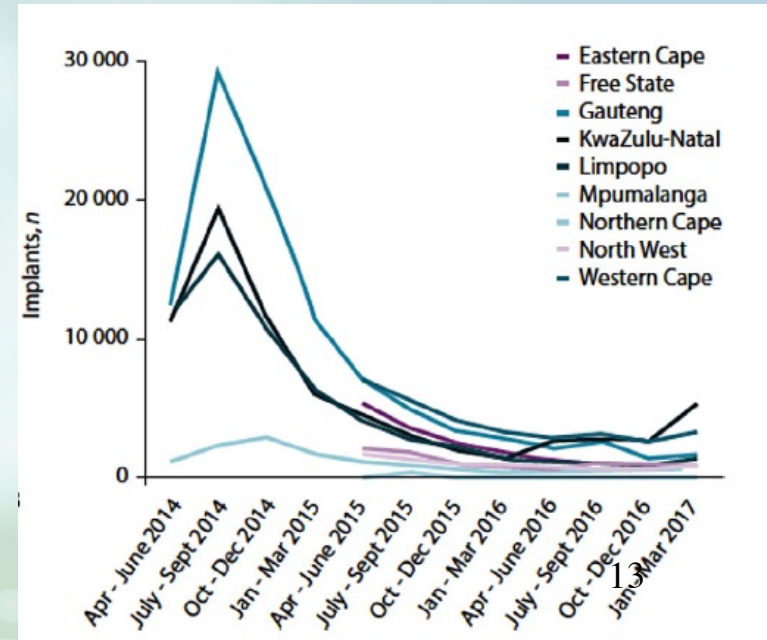
How much will it be for PrEP?

INFORMED choice is Key

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- Lessons learned from LARCs promotion in the US (tiered-effectiveness patient counseling): Ensure that people who want these methods have access to the full range of options without coercion.
- Implant rollout in RSA: decline in uptake, early implant removals & challenges in service delivery ->
 - Inadequate HCP provider training
 - Lack of patient-centered counseling
 - Inadequate provision of Information about side effects
 - Rumors and misconceptions



Pleaser 2017, Krogstad, 2020, Brandi 2019



MTN034/REACH: a RCT focusing on Choice

“Vaginal ring”



“Oral PrEP”



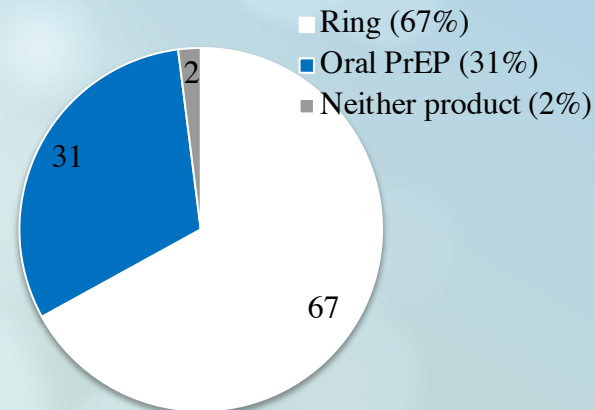
Period 1
crossover



Period 2
crossover

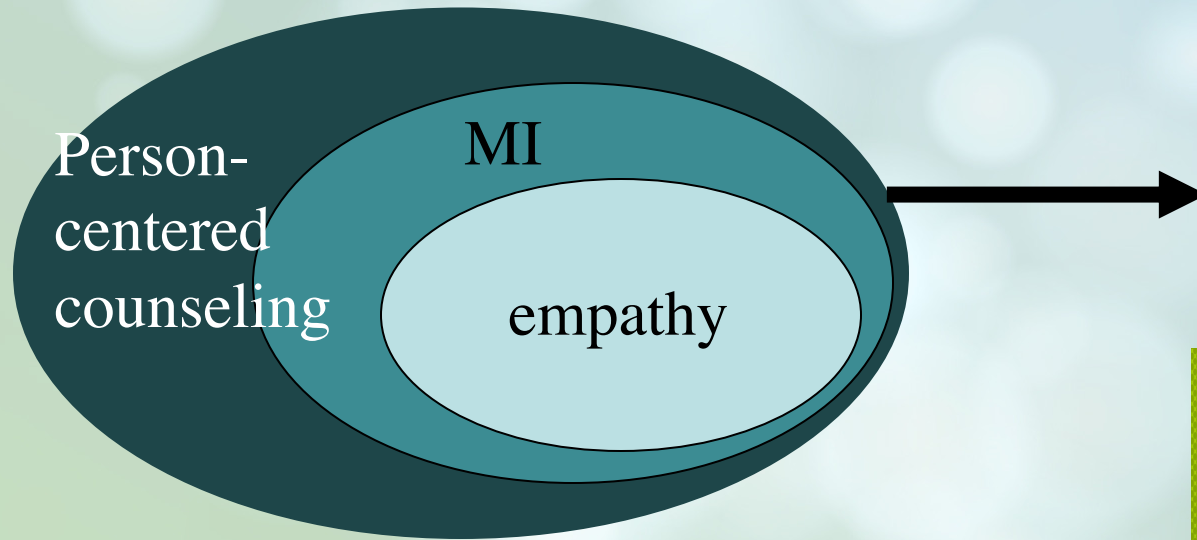


Choice
period





Provider-Participant relationship



Menu of
Adherence
support



Adherence Support Menu

- Daily Text Message**
Once a day, we will send you an automated text message to help remind you to use your study product. You will choose from several message options.
- Weekly Check-in**
 - Via Text Message** – once per week, you will receive an automated text message asking if you are OK. You will be expected to respond “OK” or “not OK”. If you don’t respond within 24 hours, a second message will be sent. If you respond “not OK”, a study team member will call you.
 - Via Phone Call** – once per week, you will receive a phone call from a study team member asking if you are OK. Based on your personal preference, they will leave a voice message or not.
- Peer Buddy**
We will connect you with another participant who is also interested in having an adherence buddy. We will help you and your “buddy” develop a plan to support each other’s adherence.

MTN-034, V3.0, 30 Jan 2018

Roberts, 2023 (forthcoming)



Study-supported informed Choice

Informed choice for HIV prevention was – itself – a strategy for overcoming challenges with product use

Overcoming challenges led to reaching HIV prevention goals

Reaching HIV prevention goals **empowered** participants to feel more **agency** over broader life goals





Shared decision-making approach

Fig. 1 Applying principles of reproductive justice to sexual and reproductive health technologies

	LARC	HIV Prevention Technologies
Center Those Who Historically Have Been Marginalized and Excluded	<ul style="list-style-type: none"> • Acknowledge the historical & social context of healthcare visits • Acknowledge individuals' lived experience 	<ul style="list-style-type: none"> • Acknowledge the historical & social context of healthcare visits • Acknowledge individuals' lived experience
Eliminate Barriers and Create Systems to Facilitate Access	<ul style="list-style-type: none"> • Appropriately describe what LARCs are, including side effects • Make methods readily available to those who want them 	<ul style="list-style-type: none"> • Appropriately describe what the HIV prevention technology is, including side effects • Make methods readily available to those who want them
Provide Person-Centered Services	<ul style="list-style-type: none"> • Respect the decision of those who choose not to use LARC • Assist those who wish to discontinue LARC • Maintain focus on meeting individual's needs, rather than a public health goal 	<ul style="list-style-type: none"> • Respect the decision of those who choose not to use HIV prevention technologies • Assist those who wish to discontinue HIV prevention technologies • Maintain focus on meeting individual's needs, rather than a public health goal

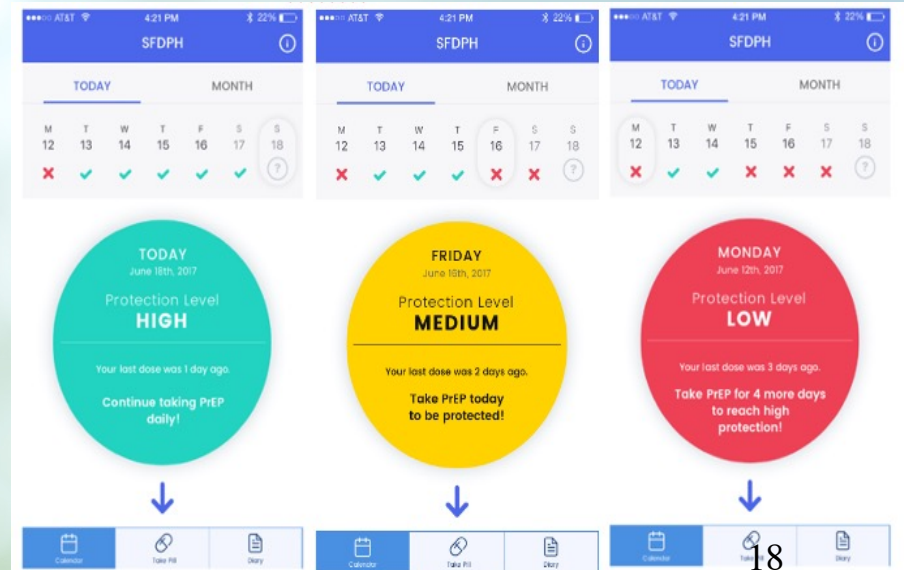
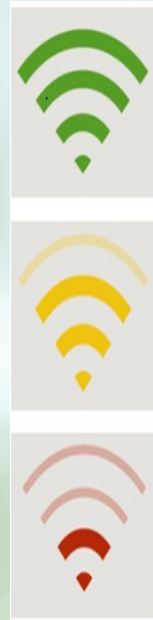
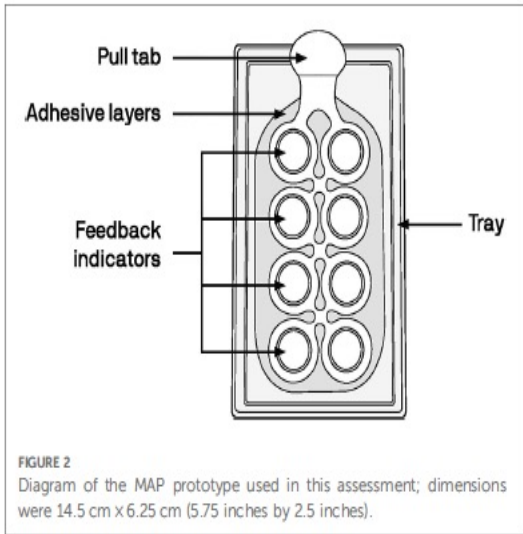


5. Tools to support Adherence

Ensuring correct application (MAP)

Visually Intuitive DLF

Self-monitoring of protection levels (DOT-DIARY)





Summary and conclusion

- Long(er)- acting strategies can be **transformative**
- **BUT: innovative biomedical products** require concurrent **innovation in:**
 - Shared or client-centered **decision-making devoid of coercion** or HCP **bias**
 - User and HCP **relationship quality** (trust, non-judgmental etc..)
 - **Informed choice** driven by personal preference and circumstances
 - **Improved access**, especially to those not currently using PrEP/Rx
 - **Support tools** and **people** to mitigate/overcome adherence challenges
- Adherence is a journey (and not a lonely one): allow opportunities to **change, switch or pause** Px/Rx strategies



Acknowledgments

MK Shapley-Quinn

Ngure, K. → Correlates of adherence in REACH, Tuesday Oral #1308



DOT Diary
Study

J. Velloza

S. Buchbinder



Monday Poster #1211



Ginny Fonner

Lara Lorenzetti





Thank you!

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Engagement into care: Rx (& PrEP) Journey

